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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,743	01/10/2001	Jorg Kleiber	101614-00010	1340

7590

07/30/2002

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 07/30/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/56743

Applicant(s)

Xtreme

Examiner

Naff

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/29/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 13-26 is/are pending in the application.
- Of the above claim(s) 13-18 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 19-28 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) File 11/10/01
- ☐ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The preliminary amendment of 1/10/01 has been entered. The amendment canceled claims 1-12 and added claims 13-26.

In a response of 4/29/02 to a restriction requirement of 3/27/02, applicants elected claims 19-26 of Group II.

5 Claims 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 8 (filed 4/29/02).

Claims examined on the merits are 19-26.

10 Claims 19-22 are objected to because of the following informalities: the claims are dependent on a nonelected claim. Appropriate correction is required.

The disclosure is objected to because of the following informalities:

15 The specification does not contain headings designating different sections.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

20

Arrangement of the Specification

25 The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- 30 (a) Title of the Invention.
 (b) Cross-References to Related Applications.
 (c) Statement Regarding Federally Sponsored Research or Development.
 (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).

- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- 5 (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- 10 (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The following insertion of headings is suggested:

page 1,

15 between the title and line 1, insert --

BACKGROUND OF THE INVENTION

Field of the Invention --.

between lines 6 and 7, insert --

Description of the Related Art --.

20 page 2, between lines 21 and 22, insert --

SUMMARY OF THE INVENTION --.

page 3, between lines 2 and 3, insert --

BRIEF DESCRIPTION OF THE DRAWINGS --.

Under this heading insert the description of the drawing at page 12,
25 lines 19-24, and cancel lines 19-24 on page 12.

Following the description of the drawings inserted on page 3,
insert --

DETAILED DESCRIPTION OF THE INVENTION --.

Appropriate correction is required.

30 Claims 19-26 are rejected under 35 U.S.C. 103(a) as being
unpatentable over Groves et al (European 0 343 934) in view of Palladino

(5,458,813) and Falleroni et al (4,824,712) and Woodard et al (5,503,816) or Padhye et al (5,658,548).

Claim 17 is drawn to a magnetic particle having a magnetic core and an outer glass layer comprising boron oxide and which completely covers
5 the magnetic core.

Claims 19-26 are require a method of separating biological material such as nucleic acids from a fluid by contacting the biological material with the magnetic particles so that the material binds to the particles and separating the biological material from the particles.

10 Groves et al disclose magnetic particles having a core of magnetic material encapsulated in a metal oxide coating. The metal oxide can be SiO_2 which provides numerous reactive sites for binding to molecules of biological interest (col 4, lines 29-35), and which can be derived from a metal alkoxide (col 4, lines 3 and 9). Each core particle is completely
15 coated with the metal oxide (col 3, lines 20-22, and col 6, lines 38-43). The magnetic particles are prepared by mixing a solution of magnetic material with a sol of the alkoxide, emulsifying the resultant mixture in an immiscible liquid to form droplets, gelling the droplets to form gel particles, de-watering the gel particles, and heating the gel particles
20 to a temperature of 250 to 2000° C. For example, see col 4, lines 57-65; col 5, lines 1-5 and col 6, lines 44-48.

Palladino discloses introducing a boron compound such as B_2O_3 into porous gels obtained by the sol-gel technique. In this technique, a sol of a precursor such as an alkoxide of a metal oxide such as SiO_2 in
25 alcohol is hydrolyzed, gelled, dried and sintered to form glass (col 1,

lines 5-67; col 3, line 13; and 3, line 46 to col 4, line 39). Further disclosed is that boron is present in a large number of technically or commercially important glasses. Boron in glass has advantages of extending the crystallinity range and lowering the sintering temperature of glasses manufactured by the sol-gel technique (col 2, lines 25-35).

Falleroni et al disclose coating a scored glass surface with a silica-boron sol-gel composition, drying the coating and heating the dried coating to about 650° C to form a glass coating.

Woodard et al (col 2, lines 53-55) disclose that it is known to use silicon-containing materials such as glass powder to purify DNA. Further disclosed is binding DNA in a fluid to boron silicate and eluting the DNA to obtain purified DNA (col 3, lines 24-45).

Padhye et al (col 2, lines 61-68) disclose that it is known to use silica materials such as glass particles to separate DNA from other substances. Further disclosed is the use of a mixture of silica gel and glass particles to separate DNA (col 3, lines 21-42).

When the metal oxide of Groves et al is SiO₂, the core of magnetic material is encapsulated completely with a non-porous or essentially non-porous glass layer, and the magnetic particles are the same as presently claimed except for the glass containing boron oxide.

It would have been obvious to provide boron oxide in the glass layer of Groves et al to obtain its function in glass as disclosed by Palladino when preparing glass containing boron oxide, i.e. to extend the crystallinity range and lower the sintering temperature, and as suggested by Falleroni et al forming a glass coating by the sol-gel technique using

a silica-boron sol-gel composition. Since Groves et al disclose that the magnetic particles can be used to couple biological molecules, and can be used for affinity chromatography (col 7, lines 21-32), it would have been obvious to use the magnetic particles of Groves et al, when produced as
5 set forth above, to purify nucleic acids as suggested by Woodard et al or Padhye et al disclosing the use of glass particles to purify DNA.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension
10 of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re*
15 *Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this
20 application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-26 are rejected under the judicially created doctrine of
25 obviousness-type double patenting as being unpatentable over claims 1-11

of U.S. Patent No. 6,255,477 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims would have been obvious from the magnetic particles and method of their use claimed by the patent.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

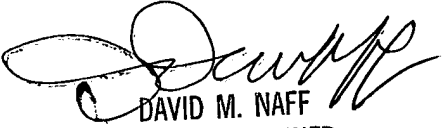
10 If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

15 The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1204

DMN

25 7/29/02